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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,910	09/09/2003	Kenichi Chiba	2003946-0056 (ANDI/CIP)	5169
24280	7590	01/26/2005	EXAMINER	
Choate, Hall & Stewart			TRINH, BA K	
Exchange Place			ART UNIT	
53 State Street			PAPER NUMBER	
Boston, MA 02109			1625	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/657,910

**Applicant(s)**

CHIBA ET AL.

**Examiner**

Ba K. Trinh

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07/11/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 36-45 is/are rejected.
- 7) ☒ Claim(s) 21-35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/14/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-45 are pending.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,6-7,36-42,44-45 are rejected under 35 U.S.C. 102(a) as being anticipated by compounds 1,2,4 and 8-13 in pages 4-5 of WO 02/48136.

Claims 1-3,6-7,36-42,44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by compound I in the Abstract of GB 2,323,845, compound I in the Abstract of EP 606,044, compound in Figure 1 page 1079 of Dombrowski et al ( J. Antibiot.,52(12), 1999), compounds in Tables 2 and 3 in pages 1090-1091 of Zhao et al ( J. Antibiot. 52(12), 1999), compounds in claim 1 of Giese et al ( US 5,795,910 ),and compounds in Figure 1 page 373 of Agatsuma et al ( Chem. Pharm. Bull, 41(2) 1993).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20,36-42 and 44-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for X being Oxygen, Y being CHR<sub>17</sub>, CR<sub>17</sub>, or NR<sub>17</sub>, Z being CHR<sub>18</sub>, C=O, CR<sub>18</sub>, or NR<sub>18</sub>, does not reasonably provide enablement for X being NH, N-alkyl, CH<sub>2</sub> or S, Y being O, C=O and Z being Oxygen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and/or use the invention commensurate in scope with these claims. The current compounds are macrocyclic compounds having complicated structures. The processes of making the same require various steps and distinct reagents and reaction conditions which are distinct one from the other. Undue experimentation are needed to obtain the current compounds.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-41 and 43-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “ inhibit production of a pro-inflammatory and/or immunologic cytokine “ and the term “autoimmune disorder” fail to specifically define an art-recognized disease to be treated. There are numerous kinds of cancerous diseases. The claims fail to show which compounds can be used to treat the specific diseases from the long list of the current diseases. It appears that the current compounds embraces a set of distinct compounds and it is not certain that whether they possess all or part of the disclosed diseases, and which compounds are essential for what diseases.

Claims 21-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

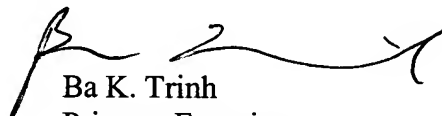
No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ba K. Trinh whose telephone number is (571) 272-0695. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Ba K. Trinh  
Primary Examiner  
Art Unit 1625

TRINH/BKT  
24 January 2005